

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application, pursuant to and consistent with 37 C.F.R. §§ 1.111 and 1.176(a), are respectfully requested.

I. Status

As is correctly reflected in the Office Action Summary, Claims 1-63 were pending in this reissue application prior to the instant amendments. *Office Action mailed April 4, 2006, Office Action Summary, Item 4.* Claims 1-63 stand rejected. *Id. at Item 6.* The drawings filed on June 27, 2003, have been accepted by the Examiner. *Id. at Item 10.*

II. Summary of Amendments

By the foregoing amendments, Applicants amended the title to correct a typographical error. The title now reads, "IGF-1 To Improve Neural Outcome." This amendment is clerical in nature and no new matter has been added.

Further by the foregoing amendments, Applicants added issued Claims 1-15 from U.S. Patent No. 5,714,460 ("the '460 patent") on which this reissue application is based. Applicants then canceled original Claims 1-15 without prejudice or disclaimer and renumbered what had been Claims 1-48 as Claims 16-63. Applicants have canceled Claims 27, 39, and 40-63 without prejudice or disclaimer. Applicants have amended the remaining claims, as needed, to reflect accurate dependency. Support for these amendments may be found in issued Claims 1-15 of the '460 patent and in original Claims 1-48 of this reissue application. Accordingly, no new matter has been added.

Further by the foregoing amendments, Applicants have amended independent Claim 16 to specify that "said CNS injury predominantly affects glia." Support for this amendment

may be found throughout the '460 patent, at least at the Abstract and at Column 1, Lines 47-61. Accordingly, no new matter has been added.

Further by the foregoing amendments, Applicants have amended independent Claim 28 to specify that "said CNS injury predominantly affects glia" and that the biological analog of IGF-1 "is selected from the group consisting of naturally-occurring analogs, IGF-2, and des 1-3 IGF-1." Support for these amendments may be found throughout the '460 patent, and at least at the Abstract; Column 1, Lines 47-61; Column 3, Lines 35-36; and Column 3, Lines 43-45. Accordingly, no new matter has been added.

Finally by the foregoing amendments, Applicants have added new Claims 64 and 65, which reflect the content of former dependent Claims 46 and 58, yet re-written in independent form. The Examiner indicated that former Claims 46 and 58 were novel and unobvious over the prior art of record or any combination thereof, as discussed below. New Claims 64 and 65 are supported at least by former Claims 40, 46, 52, and 58. Accordingly, no new matter has been added.

III. Personal Interview Conducted On June 27, 2006

Applicants and their undersigned representative thank Examiner Russel for the courtesies he extended during the personal interview ("Interview") conducted on June 27, 2006. *See Interview Summary dated June 27, 2006.* As is correctly reflected on the Interview Summary, during the Interview possible claim language focusing on treatment of glial and/or non-cholinergic diseases, in particular, and diseases which predominantly affect these types of cells were discussed. *Id.* Also discussed were issues of inherency raised by the publications of record. *Id.* Finally, Interference No. 104,553 and the Decision therein were discussed. *Id.*

IV. Assignment

The application was objected to under 37 C.F.R. § 1.172(a) because the Examiner believes that the assignee has not established its ownership interest in the patent for which reissue is being requested, *i.e.*, U.S. Patent No. 5,714,460 (“the ‘460 patent”). *See Office Action mailed April 4, 2006, Page 2, ¶ 2.* Specifically, the Examiner believes that the Offers to Surrender and Consents of the Assignees were “contradictory” in that “[t]wo separate legal entities cannot each be the owner of the entire right, title and interest in a single U.S. patent.” *Id.* Applicants respectfully disagree.

As set forth in 35 U.S.C. § 261, “[s]ubject to the provisions of this title, patents shall have the attributes of personal property.” Pursuant to 35 U.S.C. § 262, “[i]n the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, *without the consent of and without accounting to the other owners.*” (emphasis added). Finally, pursuant to 37 C.F.R. § 3.1, “*Assignment* means a transfer by a party of all or part of its right, title and interest in a patent, patent application, registered mark or a mark for which an application to register has been filed.” These provisions provide that co-inventors, together, are considered one entity and that each co-inventor owns the undivided whole invention. Such co-inventors may independently transfer their initial, complete right in the patent. As such, two assignees can together own the entire right, title, and interest in a patent.

As set forth in M.P.E.P. § 301 IV, “Joint ownership – Multiple parties may **together** own the entire right, title and interest of the patent property. This occurs when any of the following cases exist: (A) Multiple partial assignees of the patent property; (B) Multiple inventors who have not assigned their right, title and interest; or (C) A combination of partial assignee(s), and inventor(s) who have not assigned their right, title and interest. . . . All

parties having any portion of the ownership in the patent property must act **together** as a composite entity in patent matters before the Office.”

Applicants respectfully submit that the owners acted together, as required, with their Offers to Surrender and Assents of Assignees. However, Applicants and their undersigned representative will revisit the assignment and ownership situation for this reissue application and will alert the Examiner accordingly.

V. Continuing Obligations Under 37 C.F.R. § 1.178(b) And 37 C.F.R. § 1.56

The Examiner has reminded Applicants of their “continuing obligation under 37 C.F.R. § 1.178(b) to timely apprise the Office of any prior or concurrent proceeding in which Patent No. [5,714,460] is or was involved” and their “continuing obligation under 37 C.F.R. § 1.56 to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.” *See Office Action mailed April 4, 2006, Page 3, ¶ 3.*

Applicants acknowledge their obligations and will alert the Office, as necessary.

VI. Numbering of Claims

The Examiner noted that when the new claims, 1-48, were filed, their numbering should have started with number 16, not number 1, pursuant to 37 C.F.R. § 1.173(e). *See Office Action mailed April 4, 2006, Page 3, ¶ 4.* The Examiner renumbered what had been Claims 1-48 as Claims 16-63, respectively, and asked that Applicants submit a new set of claims in appropriate amendment form. *Id.*

By the instant Amendment and Reply, Applicants have complied with the Examiner's request.

VII. Claim For Priority

The Examiner indicated that “there is no claim for priority under 35 U.S.C. 119(a)-(d) present in this reissue application.” *See Office Action mailed April 4, 2006, Pages 3-4, ¶ 5.* The Examiner indicated that “[a] claim for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application, even though such a claim was previously made in the application for the original patent to be reissued.” *Id.*

The Official Filing Receipt for this reissue application correctly reflects that this application is a reissue of U.S. Patent No. 5,714,460, which issued from U.S. Patent Application Serial No. 08/460,365, filed June 2, 1995, which is a continuation-in-part of U.S. Patent Application Serial No. 08/185,804, filed January 28, 1994, now abandoned; which is a 35 U.S.C. § 371 application from PCT/US92/06389, filed August 3, 1992. The PCT application was filed from New Zealand Patent Application 239211, filed August 1, 1991. Applicants have amended the Specification to reflect these priority claims, as recommended by the Examiner.

VIII. Reissue Oath/Declaration

The Examiner has indicated that the reissue Oath/Declaration filed with the application is “defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant.” *See Office Action mailed April 4, 2006, Page 4, ¶ 6.* In addition, the Examiner rejected Claims 1-63 as being based upon a defective reissue declaration under 35 U.S.C. § 251. *Id.* These rejections are respectfully traversed.

Applicants hereby provide with the instant Amendment and Reply *an unexecuted* revised Reissue Oath/Declaration that will, upon execution, render the foregoing Examiner

concerns moot. The executed revised Reissue Oath/Declaration will be submitted as soon as possible, hopefully before the Examiner acts upon this Amendment and Reply. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 251 rejection.

IX. Rejection Under 35 U.S.C. § 102(g)

A. Claims 1-15

Claims 1-15 were rejected under 35 U.S.C. § 102(g)(1) “as being estopped on the merits by final judgment in Interference No. 104,553 . . . it was held that Gluckman is not entitled to a patent containing claims 1-15 of U.S. Patent No. 5,714,460, which correspond to Count 1 of the interference.” *See Office Action mailed April 4, 2006, Pages 4-5, ¶ 9.*

By the instant Amendment, Applicants have canceled Claims 1-15. Applicants believe this amendment has rendered moot the rejection under 35 U.S.C. § 102(g)(1), and respectfully request withdrawal thereof.

B. Claims 16-18, 23-30, 35-42, 47-54, And 59-63

Claims 16-18, 23-30, 35-42, 47-54, and 59-63 were rejected under 35 U.S.C. § 102(g) as being estopped on the merits by final judgment in Interference No. 104,553. *See Office Action mailed April 4, 2006, Pages 5-6, ¶ 10.* This rejection is respectfully traversed.

By way of background, Applicants note that Interference No. 104,553 was declared on the basis that Gluckman's '460 patent claims, while directed to “treating neural damage suffered after a CNS insult affecting glia or other non-cholinergic cells in a mammal,” did not specifically state that the CNS injury was one which predominantly affects glia or other non-cholinergic cells in a mammal. *See, Interference Initial Memorandum and Decision in*

Interference No. 104,553, particularly at footnote 15. In contrast, the Lewis application-in-interference was directed to treating neural damage affecting cholinergic cells.¹

The present reissue claims are now directed specifically to the treatment of CNS injury which affects predominantly glial cells. As noted in the Decision in Interference 104,553, Gluckman was not able to add such claims during the interference and request that they be designated as not corresponding to the Count (because of interference procedural limitations), but should not be estopped from filing a reissue application directed to the same.

As such, not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claim 16 to specify that "said CNS injury predominantly affects glia" and have amended Claim 28 to similarly specify that "said CNS injury predominantly affects glia" and that the biological analog of IGF-1 is "selected from the group consisting of naturally-occurring analogs, IGF-2, and des 1-3 IGF-1."

Applicants respectfully submit that these amendments render moot the 35 U.S.C. § 102(g) rejection and that interference estoppel should not apply to these amended claims. *See, e.g., Footnote 17 to the Decision in Interference 104,553.* Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(g) rejection.

¹ Applicants acknowledge that the Lewis disclosure contains a fleeting reference to treatment of Parkinson's Disease. While Lewis referred to Parkinson's Disease as a disease of cholinergic cells, it is actually a disease affecting predominantly non-cholinergic cells. Applicants submit that Lewis did not appreciate at the time it filed its application in interference that Parkinson's Disease was a disease affecting non-cholinergic cells, and that its reference to the same was not reflective of such a recognition. However, because of the fortuitous (for Lewis) mention of Parkinson's Disease in the Lewis application, Applicants have, merely for the purposes of expediting prosecution, canceled claims directed to Parkinson's Disease and treatment of non-cholinergic cells. Applicants do not, however, concede that the Lewis disclosure is sufficient to render these claims unpatentable.

X. Rejections Under 35 U.S.C. § 102

A. Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63

Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63 were rejected under 35 U.S.C. § 102(b) as purportedly anticipated by International Patent Application WO 90/14838 to Lewis *et al.* (“Lewis”). See *Office Action mailed April 4, 2006, Pages 6-8, ¶¶ 11-12*. This rejection is respectfully traversed.

“Invalidity based on ‘anticipation’ requires that the invention is not in fact new.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (quoting *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995)). “A single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve*, 311 F.3d at 1120 (citing *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). Put differently, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Applicants respectfully submit that Lewis fails to contain each and every element of amended Claims 16-18, 23-25, 28-30, and 35-37. Specifically, nowhere does Lewis disclose the treatment of CNS injury which predominantly affects glial cells. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection thereof over Lewis.

B. Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63

Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63 were rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Lewis in view of M. A. Lesniak *et al.*, “*Receptors for Insulin-like Growth Factors I and II: Autoradiographic Localization in Rat Brain and Comparison to Receptors for Insulin*,” 123(4) ENDOCRINOLOGY 2089-2099 (1988) (“Lesniak”), B. Knusel *et al.*, “*Selective and Nonselective Stimulation of Central Cholinergic*

and Dopaminergic Development in vitro by Nerve Growth Factor, Basic Fibroblast Growth Factor, Epidermal Growth Factor, Insulin and the Insulin-like Growth Factors I and II,” 10(2) JOURNAL OF NEUROSCIENCE 558-570 (Feb. 1990) (“Knusel”), or W. Kiess *et al.*, “*Rat C6 Glial Cells Synthesize Insulin-Like Growth Factor I (IGF-I) and Express IGF-I Receptors and IGF-II/Mannose 6-Phosphate Receptors,*” 124(4) ENDOCRINOLOGY 1727-1736 (Apr. 1989) (“Kiess”). See *Office Action* mailed April 4, 2006, Pages 8-9, ¶ 13. This rejection is respectfully traversed.

As explained above, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference.” *Verdegaal*, 814 F.2d at 631 (emphasis added). Applicants respectfully submit that Lewis fails to anticipate Applicants’ claims. Specifically, nowhere does Lewis disclose the treatment of CNS injury which predominantly affects glial cells. Furthermore, it is not proper, under an anticipation analysis, to call upon Lesniak, Knusel, and/or Kiess. Even if it were proper to call upon more than one publication to demonstrate anticipation, Applicants submit that Claims 6-18, 23-25, 28-30, and 35-37 are not anticipated because Lesniak, Knusel, and Kiess fail to disclose each and every element of those claims.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection of amended Claims 16-18, 23-25, 28-30, and 35-37 over Lewis in view of Lesniak, Knusel, and/or Kiess.

C. Claims 16-21, 28-33, 40-45, and 52-57

Claims 16-21, 28-33, 40-45, and 52-57 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by P. Gluckman *et al.*, “*A Role For IGF-I in the Rescue of CNS Neurons Following Hypoxic-Ischemic Injury,*” 182(2) BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS 593-599 (Jan. 31, 1992) (“Gluckman”). See *Office Action* mailed April 4, 2006, Pages 9-10, ¶ 14. This rejection is respectfully traversed.

The present application claims priority to New Zealand Patent Application 239211, filed August 1, 1991, which is prior to the publication date of Gluckman. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(a) rejection thereof over Gluckman.

D. Claims 28, 36-38, 52, and 60-62

Claims 28, 36-38, 52, and 60-62 were rejected under 35 U.S.C. § 102(e) as purportedly anticipated by U.S. Patent No. 5,219,837 to Cohen *et al.* ("Cohen"). *See Office Action mailed April 4, 2006, Pages 10-11, ¶ 15.* This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claim 28 to specify that "said CNS injury predominantly affects glia" and that the biological analog of IGF-1 is "selected from the group consisting of naturally-occurring analogs, IGF-2, and des 1-3 IGF-1."

Applicants believe that Cohen fails to contain each and every element of amended Claims 28 and 36-38. As such, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejection thereof over Cohen.

XI. Claims 22, 34, 46, And 58 Are Novel And Unobvious

Applicants note with appreciation that the Examiner stated that "Claims 22, 34, 46, and 58 are novel and unobvious over the prior art of record or any combination thereof." *See Office Action mailed April 4, 2006, Page 11, ¶ 16.* Because Claims 46 and 58 had each depended on a now-canceled claim, Applicants have added new Claims 64 and 65 which are directed to the subject matter of former Claims 46 and 58, respectively, albeit re-written in independent form.

Accordingly, Applicants believe Claims 22, 34, 64, and 65 are in condition for allowance.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.


In the event that there are any questions relating to this Amendment and Reply or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6000 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2518.

Respectfully submitted,
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